CLINICAL REFERENCE LABORATORY

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RECEIVED 10/9

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CSAP
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RE: Comments

1. The "extensive literature review" and the unacceptably small paired measurements study used to determine criteria for a substituted specimen has led directly to numerous lawsuits and enormous other costs levied upon certified labs. This absurd definition, with the present retest guidance, does not consider lab-to-lab or even day-to-day variation in creatinine and specific gravity measurements. This all arises from some of our program people with overly inflated egos being allowed to proclaim as "scientifically sound" a situation (substitution) with parameters that cannot be consistent. Please consider simplification, i.e.,

   Any urine with a creatinine concentration less than 20 mg/dl will go to GC/MS analysis for those analytes which give an immunoassay response at 50% or greater than the cutoff. If GC/MS analysis shows analyte present at 40% or greater of the confirmation cutoff, a positive report results. Absence of drug at these cutoffs results in a report of dilute, except...

   Any specimen with a creatinine concentration less than 10 mg/dl will be reported invalid if no drugs are detected. A recollection will be required with instruction on providing a valid (creatinine $\geq$10) specimen. A second invalid specimen would require SAP evaluation before the drug test requirement can be considered met.

PLEASE NOTE:

We turn out more negative reports on drug users who have successfully diluted their urine drug concentration to 50-99% of the initial cutoff (creatinine >5, <20) in one day than we turn out "substituted" reports in six months. The above scheme would fix this.

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2. Please define ""specific validity tests for oxidizing adulterants". There are probably a thousand oxidizing agents on the shelves that could be used successfully as an adulterant. How can a lab perform "specific" tests for each? Are you promoting a "LARK" type reagent...and if so, how is a confirmation performed to meet your specificity requirements? If, on the other hand, you restrict validity tests to detecting "nitrites, chromates, and halogens", how are you addressing STEALTH, et. al? Perhaps the collection sites should assume more of the responsibility for assuring that unadulterated specimens reach the labs.

Sincerely,

Stanley C. Kammerer, Ph.D.
Vice President & Director of Toxicology

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